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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,686	03/09/2001	Gary Van Nest	377882000900	9981

25226 7590 04/28/2009

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EXAMINER	
LE, EMILY M	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
04/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/802,686	VAN NEST, GARY	
	Examiner	Art Unit	
	EMILY M. LE	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,8-10,16 and 17* is/are pending in the application.

4a) Of the above claim(s) *4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,8-10,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/12/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claim(s)

1. Claims 2, 6-7, 11-15 and 18 are cancelled. Claims 1, 3-5, 8-10 and 16-17 are pending and under examination.

Election/Restrictions

2. Newly amended claim 4 directed to a species of CpG oligonucleotide that is independent or distinct from the invention originally claimed for the following reasons: It is structurally distinct from the other listed species of sequences presented because no significant structural similarities can be readily ascertained between the GACGTTCG motif and TGACTGTGAACGTTCGAGATGA (SEQ ID NO: 1).

Since applicant has received an action on the merits for the originally presented species of oligonucleotide, SEQ ID NO: 1, this species has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 4 is withdrawn from consideration as being directed to a non-elected species. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 3, 5, 8-10 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al.,[1] as applied to claims 1 and 3, in view of Raz, E.[2]

In response to the original rejection of claims 1 and 3-5 as being obvious over Wagner et al., as applied to claims 1 and 3, in view of Raz et al., Applicant argues that that Wagner et al. do not teach or suggest an immunostimulatory sequence (ISS) that comprises the sequence CTGGCG. Applicant's also argues that there is no reasonable expectation of success that the claimed method to suppress RSV infection could be developed using an ISS comprising the sequence CGTTCG. Applicant also argues that Wagner et al. do not teach or suggest the particular combination of disease, ISS sequence, timing and site of administration as recited in the claims. Applicant additionally specifically argues that Wagner et al. do not suggest or appreciate the mechanism of each condition is distinct and that the administration route is important, wherein the claimed administration route is local administration. Overall, Applicant argues that Wagner et al. does not teach or suggest the claimed invention.

Applicant's arguments have been considered, however, it is not found persuasive. Had Wagner et al. teaches the ISS that comprises the sequence CTGGCG or combination of disease, ISS sequence, timing and site of administration as recited in the claim; Wagner et al. would have been cited as anticipatory to the claimed invention. Rather, the instant rejection is an obviousness rejection. Regarding Applicant's assertion that Wagner et al. does not suggest an ISS that comprises the sequence

[1] Wagner et al. U.S. PreGrant Publication No. 2004/0030118, which is a continuation of 09/241653, which was filed on 02/02/1999.
[2] Raz, E. U.S. PreGrant Publication No. 2003/0092663, which has priority to U.S. Patent No. 6498148, which was filed 01/21/1999.

CTGGCG, it should be noted that Wagner et al. suggests and reasonably expects the administration of an ISS that comprises the CG motif, including the AACGTT sequence, to a subject that is at risk of RSV infection. [Claims 19-36, in particular.] It should further be noted that Wagner et al. does recognize that the route of administration is important for Wagner et al. does teach local administration. [Claim 36, in particular.] Additionally, contrary to Applicant's assertion, Wagner et al. suggests the particular combination of disease, an ISS sequence, timing and site of administration as recited in the claims, as set forth in the rejection. Moreover, KSR forecloses the argument that specific teaching, suggestion, or motivation is required to support a finding of obviousness. KSR, 82 USPQ2d at 1396.

Turning to Raz, Applicant argues that Raz does not teach or suggest that to suppress an RSV infection, an ISS sequence comprising the sequence CGTTCG motif is administered locally prior to infection with RSV.

Applicant's argument has been considered, however, it is not found persuasive. Had Raz teaches the claimed invention, the Office would have readily cited Raz as anticipating the claimed invention. Additionally, had Raz solely suggests the claimed invention, the Office would have readily cited Raz by itself for rendering the claimed invention obvious. The claimed invention is rendered obvious over Wagner et al., in view of Raz.

The claims are directed to a process comprising the administration of a composition to the respiratory tract of an individual by local administration, wherein said composition comprises a polynucleotide comprising an immunostimulatory sequence

comprising the TCG motif, wherein the ISS sequence is greater than 6 and less than about 50 nucleotides in length, wherein the individual is a human and the composition is administered between 3 and 14 days before exposure to RSV. Claim 3, which depends on claim 1, requires that the ISS comprises the sequence purine-purine-CG-pyrimidine-pyrimidine. Claim 5, which depends on claim 1, requires the polynucleotide to comprise the following sequence: TGACTGTGAACGTTCGAGATGA (SEQ ID NO: 1). Claim 8, which depends on claim 1, requires that administration be to the lung. Claim 9, which depends on claim 1, requires the administration be directed to the nasal passages. Claim 10, which does not further limit the claimed invention, specifies that the suppression of RSV by performing the claimed method comprises a reduction of RSV titer in a biological sample from said individual. Claim 16, which depends on claim 1, requires that the polynucleotide to comprise a phosphate backbone modification. Claim 17, which depends on claim 1, requires that he composition comprises a pharmaceutically acceptable excipient.

Wagner et al. teaches a process comprising the administration of a composition to the respiratory tract of a subject by local administration, wherein said composition comprises a polynucleotide comprising an immunostimulatory sequence (ISS) comprising the TCG motif, wherein the ISS sequence is greater than 6 and less than about 50 nucleotides in length, wherein the composition is administered between 3 and 14 days before exposure to RSV. [Claims 19-36, in particular.] By "subject", Wagner et al. includes humans. [Paragraph 0093, in particular.] . The ISS that Wagner et al. teaches encompass those having the sequence purine-purine-CG-pyrimidine-

pyrimidine. [Sequence listing, in particular.] Wagner et al. teaches that the administration be intranasal, the nasal passages and to the lungs, and that the polynucleotide have comprise a phosphate backbone modification.

Wagner et al. does not teach a polynucleotide comprising the following: TGACTGTGAACGTTCGAGATGA. However, Wagner et al. does suggest the use of polynucleotide comprising the CpG motif. At the time the invention was made, Raz, E. teaches a polynucleotide comprising TGACTGTGAACGTTCGAGATG, which Raz, E. designates as SEQ ID NO: 19. Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to use the polynucleotide of Raz, E. as an alternative to the polynucleotide used by Wagner et al. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to induce an immune response in the subject. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the substitution of known alternatives is routinely practiced in the art.

Additionally, Wagner et al. did not administer the composition with a pharmaceutically acceptable excipient, Wagner et al. does suggest the use of pharmaceutically acceptable excipients to facilitate delivery of the drug. Hence, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to include a pharmaceutically acceptable excipient with the composition of Wagner et al. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to facilitate the delivery of the composition. One of ordinary skill in the art, at the time the invention was made would have had a

reasonable expectation of success for doing so because the use of pharmaceutically acceptable excipients with compositions is routinely practiced in the art.

While it is noted that the preamble and wherein clause of the claims require that the method suppresses or reduces RSV titer, it should be noted that such requirement do not further limit the claims. Said preamble and wherein clause do not impart any additional functional or structural characteristic onto the claimed invention. Therefore, neither are interpreted as a limitation. Additionally, it should be noted that the Wagner et al. does not need to appreciate the RSV suppressive activity described by Applicant in order to anticipate the claimed invention for such would have been inherent of the method taught by Wagner et al. Since the method of Wagner et al. is the same as the claimed method, the method of Wagner et al. would also necessarily suppress or reduce RSV titer. MPEP 2112, which provides "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999).

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. The double patenting rejection over U. S Patent No. 10/898512 is maintained for reason(s) set forth in the record. It is noted that Applicant has stated that Applicant will address this provisional double patenting rejection with a terminal disclaimer. Applicant's intention is noted. Until the rejection is properly addressed with a terminal disclaimer, the rejection is maintained on the record.

Conclusion

7. No claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LE whose telephone number is (571)272-0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EMILY M LE/
Primary Examiner, Art Unit 1648

/E. M. L./